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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,443	06/20/2005	Anders Nykjaer	0090326-001US0	6823

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EXAMINER	
MACFARLANE, STACEY NEE	
ART UNIT	PAPER NUMBER
1649	

NOTIFICATION DATE	DELIVERY MODE
09/24/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/539,443	NYKJAER ET AL.	
	Examiner	Art Unit	
	STACEY MACFARLANE	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *73,78,81-86,88,89 and 100* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *73, 78, 81-86, 88-89 and 100* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/15/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Claim 81 has been amended as requested in the amendment filed on June 15, 2009. Following the amendment, claims 73, 78, 81-86 and 89-100 are pending in the instant application and, only in so far as they read upon the originally elected subject matter of a method of treatment using an antibody agent directed against a sequence of SEQ ID NO: 1 (Sortilin), the neurotrophin NGF, and the condition of an "injury and/or dysfunction of the central and/or peripheral nervous system", are under examination in the instant office action.

2. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3. Applicant's arguments filed on June 15, 2009 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. As currently amended, Claims 73, 78, 81-86, 88-98 and 100 stand rejected under 35 U.S.C. 112, first paragraph, scope of enablement, for reasons of record in the previous Office action.

On pages 9-16 of Remarks filed October 14, 2008, Applicant traverses the rejection on the grounds that the basis for the enablement rejection is grounded on a "lack of utility". While this has been reviewed in full it is not found persuasive for the following reasons.

The factors to be considered in determining whether a disclosure would require undue experimentation include: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. *In re Wands*, 8 USPQ2d, 1400 (CAFC 1988). Whereas, the grounds for a utility rejection are based upon the analysis of a "specific", "substantial" and "credible" as provided in the Utility Examination Guidelines 60 FR 36263 (1995), at 1177 O.G. 146 (1995); and the Revised Utility Guidelines, Vol. 64, Number 244, December 21, 1999. The analysis provided in the previous Office action is based solely on the *Wands* factors, therefore, traverse directed to "utility" are moot. In applying the *Wands* factors, Examiner concludes that one of ordinary skill would not know how to "use" the invention commensurate in scope with claims, drawn to providing treatment of any injury or dysfunction of the CNS or PNS.

The Declaration of Dr. Sigrid Jusélius under 37 CFR 1.132 filed June 15, 2009 is insufficient to overcome the rejection of claims 73, 78, 81-86, 88-98 and 100 based upon 35 U.S.C. 112, first paragraph as set forth in the last Office action because: The Declaration provides no evidence in support of the instant specification providing

enablement for how to make and/or use an inhibitory anti-sortilin antibody, required by the claims. The Declaration provides only post-filing data (Appendix A and B) in support of a showing of enablement. Appendices A and B, however, utilize methodology and/or materials that is not equivalent to those described within the instant specification. Appendix A is drawn to the *in vivo* use of a propeptide of proNGF fused to GST, which has the effect of increasing survival of motor neurons. This method is not descriptive of a method comprising exposing a receptor of the Vps10p-domain receptor family to an inhibitory antibody in an animal suffering from injury or dysfunction of the CNS or PNS, required by the instant invention (claim 93). Appendix B is attributed to the Quistgaard publication (2009) in support of an inhibitory anti-sortilin antibody, however, there is no evidence for an inhibitory antibody within that disclosure, nor is there enabling support for the in vivo use of said antibody in subjects having CNS/PNS injury or dysfunction. Furthermore, the Quistgaard reference teaches a complex structural relationship for ligand binding to Sortilin, requiring polar and Van der Waals interactions (Figure 1e,f) and does not provide evidence of any fully-characterized antigenic epitope within Sortilin to which an inhibitory antibody could be easily made by routine methodology. Therefore, the declaration does not provide a preponderance of evidence that the methods disclosed in the instant specification are enable one of ordinary skill to make and/or use the invention of the instant claims drawn to a method for inhibiting the binding of pro-neurotrophin to the instantly-elected sortilin receptor comprising contacting said receptor with an inhibitory antibody. Thus, the rejection for lack of enablement is maintained for reasons of record.

Conclusion

6. No Claim is allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STACEY MACFARLANE whose telephone number is (571)270-3057. The examiner can normally be reached on M-W and F 5:30 to 2, TELEWORK-Thursdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stacey MacFarlane
Examiner
Art Unit 1649

/John D. Ulm/
Primary Examiner, Art Unit 1649